510(K) Summary - K083203

Helios II® Q-Switched Nd:YAG Laser System

Applicant:

Laseroptek Co. Ltd.

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Contact Person:

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Preparation Date:

August 16, 2008

Device Trade Name:

Helios II® Q-Switched Nd:YAG Laser System

Common Name:

Nd:YAG Pulsed Surgical Laser

Classification Name:

Instrument, Surgical, Powered laser, 79-GEX, 21

CFR 878-4810

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Helios II® Q-Switched Nd:YAG Laser System

Legally Marketed Predicate Devices:

- Fotona QX Nd:VAG/KTP Laser System, K053139, by Fotona d.d.
- Medlite C3 Q Switched Nd: YAG Laser, K011677, by Continuum Electro-Optics, Inc (now Hoya CouiBio, Inc)
- Medlite C6 Q Switched Nd: YAG Laser, K014234, by Continuum Electro-Optics, Inc (now Hoya CouiBio, Inc)

Description of the Helios II® Q-Switched Nd:YAG Laser System:

The Helios II® laser system is based on the Nd:YAG (1064 nm) and frequency doubled KTP Nd:YAG (532 nm) laser technology. Three basic elements of operations are as follows:

- 1) A Nd:YAG crystal is used as a gain medium which produces a laser beam.
- 2) A resonator then amplifies the beam.
- 3) A lamp that contains Xe gas is used, as a pumping light source. The lamp requires a high-pressure power source device for operation. When the electric energy generated from the high-pressure power source is induced into the electrode of the lamp, it converts into light energy. This converted light energy pumps the Nd:YAG crystal a gain medium and the light exhausted from the crystal is amplified into a specific wavelength light. As it passes between the resonant gases, laser beam radiates to an output unit.

The regulation of laser output and repetition rate can be set by the user via GUI (Graphic User Interface) and controlled by microprocessor, which interfaces with the power supply. K043203 p-3.+3

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Helios II® Q-Switched Nd:YAG Laser System

Intended Use of the Helios II® Q-Switched Nd:YAG Laser System:

The Helios II® Q-Switched Nd:YAG Laser System delivers continuous wave laser light in the contact or non-contact mode for;

Tattoo Removal

• dark ink: blue and black

light ink: redlight ink: sky blue

• light ink: green

Treatment of Vascular Lesions:

- port wine birthmarks
- telangiectasias
- spider angioma
- cherry angioma
- spider nevi

Treatment of Pigmented Lesions:

- café-au-lait birthmarks
- solar lentiginos
- senile lentiginos
- becker's nevi
- freckles
- nevus spilus
- nevus of ota

Performance Data:

None

Conclusion:

The Helios II® Q-Switched Nd:YAG Laser System is substantially equivalent to other existing systems in commercial distribution for treatment of the intended use indication as listed above and share very similar / exactly same performance specification parameters.





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

APR 2 8 2009

Laseroptek Co. Ltd. % DPS International Mr. Kevin J. Choi 22750 Hawthorne Boulevard #211 Torrance, California 90505

Re: K083203

Trade/Device Name: Helios II Q-Switched ND:YAG Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery

and in dermatology

Regulatory Class: II Product Code: GEX Dated: April 20, 2009 Received: April 22, 2009

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Division of General, Restorative and Neurological Devices Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K083203

Device Name:

Helios II Q-Switched ND:YAG Laser System

Indications For Use:

Incision, excision, ablation, vaporization of soft tissue for general dermatology. Removal or lightening of unwanted hair with or without adjuvant preparation.

Tattoo Removal

- · dark ink: blue and black
- light ink: red
- · light ink: sky blue
- light ink: green

Treatment of Vascular Lesions:

- · port wine birthmarks
- · telangiectasias
- · spider angioma
- · cherry angioma
- spider nevi

Treatment of Pigmented Lesions:

- café-au-lait birthmarks
- solar lentiginos
- · senile lentiginos
- becker's nevi
- freckles
- nevus spilus
- nevus of ota

(Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)			

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number <u>KU83203</u>